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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,857	08/16/2005	Boris Lin	ON/4-32633A	4424

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

PACKARD, BENJAMIN J

ART UNIT	PAPER NUMBER
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4173

MAIL DATE	DELIVERY MODE
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02/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,857	Applicant(s) LIN ET AL.	
	Examiner Benjamin Packard	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>(1 sheet)</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II (claims 1-9) and the species election of epothilone B in the reply filed on 12/19/2007 is acknowledged. The restriction/specification is made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Pardee et al (US Pregrant Pub 2002/0169135).

Pardee et al at claim 94, discloses treating multiple myeloma with G1 and/or S phase drug and G2/M phase drug. Claim 97, dependant from claim 94 and claim 96, discloses the G2/M can be a microtubule (claim 96) which is an epothilone (claim 97). Finally, at page 3 table 1, epothilone is disclosed to include A,B,C,D, or mixtures and also at page 4 paragraph 29. Additionally, paragraph 9 discloses the method is effective on cell lines resistant to regular therapies.

Art Unit: 4173

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Claims 1-3, 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pardee et al (US Pregrant Pub 2002/0169135).

Pardee et al at claim 94, discloses treating multiple myeloma with G1 and/or S phase drug and G2/M phase drug. Claim 97 discloses the G2/M can be a microtubule which is an epothilone. Finally, at page 3 table 1, epothilone is disclosed to include A,B,C,D, or mixtures and also at page 4 paragraph 29. Additionally, paragraph 9 discloses the method is effective on cell lines resistant to regular therapies.

Art Unit: 4173

Pardee et al does not specifically disclose treating myeloma and epothilone B as a preferred embodiment, nor does it disclose the administration schedule.

It would be obvious to one of ordinary skill in the art to select the components taught by Pardee et al to treat multiple myeloma as disclosed as treatable.

Generally, it is prima facie obvious to determine workable or optimal values (including administration) within a prior art disclosure through the application of routine experimentation. See *In re Aller*, 105 USPQ 233, 235 (CCPA 1955); *In re Boesch*, 205 USPQ 215 (CCPA 1980); and *In re Peterson*, 65 USPQ2d 1379 (Fed. Cir. 2003).

Therefore, one of ordinary skill in the art could easily determine the optimal administration schedule using known techniques.

Claims 1-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pardee et al (US Pregrant Pub 2002/0169135), in view of Ojima et al (US 5,811,452).

Pardee et al at claim 94, teaches treating multiple myeloma with G1 and/or S phase drug and G2/M phase drug. Claim 97 teaches the G2/M can be a microtubule which is a epothilone. Finally, at page 3 table 1, epothilone is taught to include A,B,C,D, or mixtures and also at page 4 paragraph 29. Additionally, paragraph 9 teaches the method is effective on cell lines resistant to regular therapies.

Pardee et al does not teach the observance of the overexpression of the multi-resistance protein p170 or myelomas resistant to taxane.

Art Unit: 4173

Ojima et al teaches multi-drug resistance is a result of the P-glycoprotein (p170) being overexpressed, which causes cross resistance to taxanes (column 1 lines 24-35 and lines 52-56).

One of ordinary skill in the art would recognize from Ojima et al that the treatments taught in Pardee et al are obvious for cells that have the instantly claimed properties where both sets are directed to taxane resistant cells.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-F 8-3:45 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 4173

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

29 January 2008
BP

Frederick Krass
Supervisor Art Unit 1612
